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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,815	03/16/2001	Andreas Burgard	00/067 NUT	6739

7590

09/15/2003

ProPat LLC  
CROSBY ROAD  
Charlotte, NC 28211

EXAMINER

WALLS, DIONNE A

ART UNIT

PAPER NUMBER

1731

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/810,815	BURGARD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Dionne A. Walls	1731	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4,10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,10 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-4 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/04822 in view of Mozda (US. Pat. No. 4,753,800).

WO 99/04822 discloses molar ratios of salts of a sweetener (aspartame or acesulfame, for instance) and an unpleasantly tasting pharmaceutical (see page 2). While there may be no specific teaching that nicotine may be the unpleasant-tasting drug from which a salt can be formed with the sweetener, WO 99/04822 does state that the term "drug substance", as disclosed in its specification, includes active ingredients of any human drugs, whose organoleptic properties, especially taste after taste, are unpleasant for patients (see lines 5-14). Further, Mozda states that nicotine is an unpleasant tasting drug, used as a medicament in the pharmaceutical/medical area for stimulating the nervous system (col. 3, lines 51-54, and col. 4, line 12). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize as the drug substance, from which to form (with a sweetener) a salt compound, nicotine since it is a drug known to have an unpleasant taste, as evidenced by the Mozda disclosure. Also, while there may be no specific recitation, in WO 99/04822 modified by Mozda, that the molar ratio of the nicotine-sweetener compound

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is 1:2, such differences would have been obvious to one having ordinary skill in the art as a routine modification of the product, in an effort to optimize the pleasant taste, in the absence of a showing of unexpected results. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA)

Regarding claim 4, while the product of WO 99/04822 modified by Mozda may not specifically state the use of aspartame-K, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize the potassium salt form of the aspartame sweetener since its use is conventional and widely-used in many arts.

Regarding claim 10, while WO 99/04822 modified by Mozda may not specifically state that the compound of its invention is a liquid or solid preparation in the form of a chewing gum, chewing tablet or compressed formulation, WO 99/04822 does state, that generally, an oral dosage in liquid suspension, tablet or capsule form is favored since it allows for simple and cheap dosage (page 1, lines 11-24). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to produce the pharmaceutical compound of the combined references in a liquid or solid (i.e. tablet) since producing medicaments, for ingestion, in this form is conventional.

### ***Response to Arguments***

3. Applicant's arguments filed June 30<sup>th</sup>, 2003 have been fully considered but they are not persuasive. Such arguments are considered to have been addressed in the above prior art rejection. However, in sum, the Examiner believes that the mere fact

that the nicotine-sweetener compound claimed recites a 1:2 molar value, does not define over the nicotine-sweetener compound suggested by the combined references because one having ordinary skill in the art would have performed a routine modification of the compound and arrived at the claimed 1:2 molar ratio compound in an effort to enhance to taste of the drug.

### ***Conclusion***

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

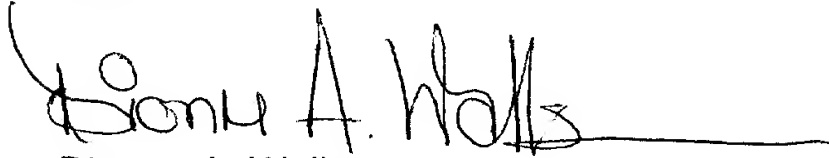
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dionne A. Walls whose telephone number is (703) 305-0933. The examiner can normally be reached on Mon-Fri, 7AM - 4:30PM (Every other Friday off).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven P. Griffin can be reached on (703) 308-1164. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

A handwritten signature in black ink, appearing to read "Dionne A. Walls", followed by a horizontal line.

Dionne A. Walls  
September 11, 2003